

10-23-06



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Docket No.: 19240.594 US1  
(PATENT)

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Andrew R. Marks Confirmation No.: 6915  
Application No.: 10/608,723 Art Unit: 1646  
Filed: June 26, 2003 Examiner: R. Li  
Title: METHODS FOR TREATING AND PREVENTING CARDIAC  
ARRHYTHMIA

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT (IDS)

Dear Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§ 1.56, 1.97 and 1.98, applicant brings to the attention of the Examiner the documents listed on the attached Form PTO SB-08. Copies of the documents listed are not submitted herewith. These documents were previously cited by or submitted to the United States Patent and Trademark Office in U.S. Patent Application No. 10/288,606, filed November 5, 2002 and is relied upon in this application for an earlier filing date under 35 U.S.C. 120.

Applicant also hereby lists the following U.S. patents/patent applications that are related to this application:

U.S. Patent No. 6,489,125, issued December 3, 2002  
U.S. Patent Application No. 10/288,606, filed November 5, 2002  
U.S. Patent Application No. 10/680,988, filed October 7, 2003  
U.S. Patent Application No. 10/763,498, filed January 22, 2004 (Abandoned)  
U.S. Patent Application No. 10/809,089, filed March 25, 2004  
U.S. Patent Application No. 11/088,123, filed March 23, 2005  
U.S. Patent Application No. 11/088,058, filed March 23, 2005  
U.S. Provisional Application No. 60/452,644, filed March 7, 2003 (Expired)  
U.S. Patent Application No. 10/794,218, filed March 5, 2004  
U.S. Provisional Application No. 60/636,959, filed December 16, 2004 (Expired)  
U.S. Patent Application No. 11/212,309, filed August 25, 2005  
U.S. Patent Application No. 11/305,528, filed December 16, 2005

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U.S. Patent Application No. 11/212,413, filed August 25, 2005

U.S. Patent Application No. 11/506,285, filed August 17, 2006

This Information Disclosure Statement is being filed after the mailing date of the first Office Action on the merits and before the mailing date of a final Office Action or a Notice of Allowance. Please charge the \$180.00 fee to our Deposit Account No. 08-0219. Applicant requests that the Examiner initial and return a copy of the enclosed Form PTO SB-08 with the next communication.

Respectfully submitted,

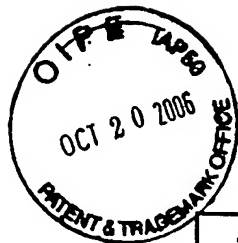
Dated: 10/20/06



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PTO/SB/08a/b (07-06)

Approved for use through 09/30/2006. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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<b>Substitute for form 1449A/B/PTO</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)			<b>Complete if Known</b>		
			Application Number	10/608,723-Conf.# - 6915	
			Filing Date	June 26, 2003	
			First Named Inventor	Andrew R. Marks	
			Art Unit	1646	
			Examiner Name	R. Li	
Sheet	1	of	3	Attorney Docket Number	19240.594 US1

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	AA*	US-3,367,930-A	02-06-1968	Schmutz et al.	
	AB*	US-5,075,293	12-24-1991	Reifschneider et al.	
	AC*	US-5,180,720	01-19-1993	Husa et al.	
	AD*	US-5,182,272	01-26-1993	Hallinan et al.	
	AE*	US-5,304,644	04-19-1994	Husa et al.	
	AF*	US-5,324,722	06-28-1994	Hagen et al.	
	AG*	US-5,354,747	10-11-1994	Hansen, Jr. et al.	
	AH*	US-5,449,675	09-12-1995	Chandrakumar et al.	
	AI*	US-5,817,652	10-06-1998	Lawrence E. Brieady	
	AJ*	US-20030054531-A1	03-20-2003	Gretarsdottir et al.	
	AK*	US-20040082653-A1	04-29-2004	Nonaka et al.	
	AL*	US-20060100195-A1	05-11-2006	Maruyama et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				
	BA	WO-92/19617	11-12-1992	Searle & Co		
	BB	WO-93/13082	11-27-1992	G.D. Searle & Co.		
	BC	WO-94/11360	05-26-1994	Boots Co Plc et al.		
	BD	WO-94/29286	12-22-1994	Searle & Co et al.		
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	BF	WO-96/08228	03-21-1996	Zambon Spa et al.		
	BG	WO-97/17344	05-15-1997	Astra Ab et al.		
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	BI	WO-01/47510	07-05-2001	Glaxo Group Limited et al.		
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	BK	WO-02/014246	02-21-2002	Bayer Aktiengesellschaft		
	BL	WO-02/014245	02-21-2002	Bayer Aktiengesellschaft		
	BM	WO-02/072145	09-19-2002	Ono Pharmaceutical Co, Ltd.		
	BN	WO-03/043655	05-30-2003	Ono Pharmaceutical Co., Ltd.		
	BO	EP-1369129	12-10-2003	Ono Pharmaceutical Co		
	BP	WO-2004/023030	03-18-2004	Nippon Chemi-con Corporation		
	BQ	WO-04/042389-A2	05-21-2004	Bayer Healthcare AG		
	BR	EP-1439221-A1	07-21-2004	F. Hoffmann-La Roche AG		
	BS	EP-1447096	08-18-2004	Ono Pharmaceutical Co		

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. \* CITE NO.: Those application(s) which are marked with an single asterisk (\*) next to the Cite No. are not supplied (under 37 CFR 1.98(a)(2)(iii)) because that application was filed after June 30, 2003 or is available in the IFW. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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Substitute for form 1449A/B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	10/608,723-Conf.# - 6915
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				First Named Inventor	Andrew R. Marks
				Art Unit	1646
				Examiner Name	R. Li
Sheet	2	of	3	Attorney Docket Number	19240.594 US1

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>	
	CA	Antos, C.L. et al.: "Dilated Cardiomyopathy and Sudden Death Resulting From Constitutive Activation of Protein Kinase A," Circulation Research, November 23, 2001. Pages 998-1004.		
	CB	Baille, et al., "beta-Arrestin-mediated PDE4 cAMP phosphodiesterase recruitment regulates beta-adrenoceptor switching from Gs to Gi," Proc. Natl. Acad. Sci. USA 100, 940-945 (2003).		
	CC	Barnes, P.J., "Theophylline: new perspectives for an old drug," Am. J. Respir. Crit. Care Med. 167, 813-8 (2003).		
	CD	Bittar, et al., "The arrhythmogenicity of theophylline. A multivariate analysis of clinical determinants," Chest 99, 1415-1420 (1991).		
	CE	Bolger, et al., "Characterization of five different proteins produced by alternatively spliced mRNAs from the human cAMP-specific phosphodiesterase PDE4D gene," Biochem. J. 328 (Pt 2), 539-48 (1997).		
	CF	Bristow, et al., "Beta 1- and beta 2-adrenergic-receptor subpopulations in nonfailing and failing human ventricular myocardium: coupling of both receptor subtypes to muscle contraction and selective beta 1-receptor down-regulation in heart failure," Circ. Res. 59, 297-309 (1986).		
	CG	Carlisle Michel, et al., "PKA-phosphorylation of PDE4D3 facilitates recruitment of the mAKAP signaling complex," Biochem. J. 381, 587-592 (2004).		
	CH	Conti, et al., "Cyclic AMP-specific PDE4 phosphodiesterases as critical components of cyclic AMP signaling," J. Biol. Chem. 278, 5493-6 (2003).		
	CI	Exhibit A: Chemical Structures		
	CJ	Feldman, et al., "Deficient production of cyclic AMP: pharmacologic evidence of an important cause of contractile dysfunction in patients with end-stage heart failure," Circulation 75, 331-9 (1987).		
	CK	Giembycz, M.A., "Development status of second generation PDE4 inhibitors for asthma and COPD: the story so far," Monaldi, Arch. Chest Dis. 57, 48-64 (2002).		
	CL	Gong, et al., "Persistent improvement in synaptic and cognitive functions in an Alzheimer mouse model after rolipram treatment," J. Clin. Invest. 114, 1624-1634 (2004)		
	CM	Gretarsdottir, et al., "The gene encoding phosphodiesterase 4D confers risk of ischemic stroke," Nat. Genet. 35, 131-8 (2003).		
	CN	Houslay, et al., "PDE4 cAMP phosphodiesterases: modular enzymes that orchestrate signaling cross-talk, desensitization and compartmentalization," Biochem. J. 370, 1-8 (2003).		
	CO	International Search Report and Written Opinion from PCT/US05/45914, August 31, 2006		
	CP	Jin, S.L.C. et al.: "Impaired growth and fertility of cAMP-specific phosphodiesterase PDE4D-deficient mice," PNAS, October 12, 1999, vol. 96, no. 21, 11998-12003.		
	CQ	Kapiloff, M.S. et al.: "mAKAP and the ryanodine receptor are part of a multi-component signaling complex on the cardiomyocyte nuclear envelope," Journal of Cell Science, 114, 3167-3176 (2001).		
	CR	Katritzky, et al., "1H and 13C NMR study of tetrahydro-1, 4-benzothiazepine conformations," J. Chem. Soc. 5, 1816-1822 (2002).		
	CS	Katritzky, et al., "Convenient syntheses of 2, 3, 4, 5-tetrahydro-1, 4-benzothiazepines, -1, 4-benzoxazepines and -1, 4-benzodiazepines," J. Chem. Soc. 11, 592-598 (2002).		
	CT	Mongillo, et al., "Fluorescence resonance energy transfer-based analysis of cAMP dynamics in live neonatal rat cardiac myocytes reveals distinct functions of compartmentalized phosphodiesterases," Cir. Res., 95, 67-75 (2004).		
	CU	Nair, et al., "Synthesis and reactions of 1, 4-benzothiazepine derivatives," IJOCAP, 7(9), 862-5 (1969).		
	CV	Packer, et al., "Effect of oral milrinone on mortality in severe chronic heart failure. The		

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Sheet	3	of	3	Attorney Docket Number	19240.594 US1

		PROMISE Study Research Group," N. Engl. J. Med. 325, 1468-75 (1991).	
	CW	Perry, et al., "Targeting of cyclic AMP degradation to beta 2-adrenergic receptors by beta-arrestins," Science 298, 834-6 (2002).	
	CX	Pieske, et al., "Ca2+ handling and sarcoplasmic reticulum Ca2+ content in isolated failing and nonfailing human myocardium," Circ. Res. 85, 38-46 (1999).	
	CY	Richter, et al., "Splice variants of the cyclic nucleotide phosphodiesterase PDE4D are differentially expressed and regulated in rat tissue," Biochem. N. 388, 803-811 (2005).	
	CZ	Ruehr, et al., "Targeting the protein kinase A by muscle A kinase-anchoring protein (mAKAP) regulates phosphorylation and function of the skeletal muscle ryanodine receptor," J. Biol. Chem. 278, 24831-24836 (2003).	
	CA1	Sette, et al., "Phosphorylation and activation of a cAMP-specific phosphodiesterase by the cAMP-dependent protein kinase. Involvement of serine 54 in the enzyme activation," J. Biol. Chem. 271, 16526-34 (1996).	
	CB1	Sette, et al., "The ratPDE3/lvd phosphodiesterase gene codes for multiple proteins differentially activated by cAMP-dependent protein kinase," J. Biol. Chem. 269, 18271-4 (1994).	
	CC1	Shannon, et al., "Elevated sarcoplasmic reticulum Ca2+ leak in intact ventricular myocytes from rabbits in heart failure," Circ. Res. 93, 592-4 (2003).	
	CD1	Suissa, et al., "Bronchodilators and acute cardiac death," Am. J. Respir. Crit. Care Med. 154, 1598-1602 (1996).	
	CE1	Tasken, et al., "Phosphodiesterase 4D and protein kinase a type II constitute a signaling unit in the centrosomal area," J. Biol. Chem. 276, 21999-2002 (2001).	
	CF1	van Rooij, et al., "MCIPI overexpression suppresses left ventricular remodeling and sustains cardiac function after myocardial infarction," Circ. Res. 94, e18-26 (2004).	
	CG1	Verde, et al., "Characterization of the cyclic nucleotide phosphodiesterase subtypes involved in the regulation of the L-type Ca2+ current in rat ventricular myocytes," Br. J. Pharmacol. 127, 65-74 (1999).	
	CH1	Vignola, A.M., "PDE4 inhibitors in COPD--a more selective approach to treatment," Respir. Med. 98, 495-503 (2004).	
	CI1	Wang, et al., "Cloning and characterization of novel PDE4D isoforms PDE4D6 and PDE4D7," Cell. Signal. 15, 883-891 (2003).	
	CJ1	Wehrens, et al., "Intracellular Calcium Release Channels and Cardiac Disease," Annu. Rev. Physiol. (2004).	
	CK1	Xiang, Y. et al., "Phosphodiesterase 4D is required for beta2 adrenoceptor subtype-specific signaling in cardiac myocytes," PNAS, January 18, 2005, Vol. 102, no. 3, 909-914.	
	CL1	Zaccolo, et al., "Discrete micro domains with high concentration of cAMP in stimulated rat neonatal cardiac myocytes," Science 295, 1711-5 (2002).	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

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Attorney Docket No.: 19240.594 US1

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